

The effect of diabetes education tailored to nurses in psychiatry

Submission date 19/09/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 02/10/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 19/11/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Diabetes is more prevalent and insufficient treated among individuals with severe mental illness, and it is an important risk for heart diseases and premature death. On average individuals with severe mental illness die 15-20 years earlier than people without severe mental illness. The aim of the present study is to develop a diabetes education tailored to psychiatric nurses and investigate the effectiveness of the education to determine whether this will lead to better diabetes care among people with both severe mental illness and diabetes.

Who can participate?

People with severe mental illness and diabetes treated in one of the eight selected psychiatric outpatient clinics are all eligible to participate.

What does the study involve?

The study involves three consecutive days of diabetes education provided to all psychiatric nurses at four psychiatric out-patient clinics in Denmark. The effectiveness of the diabetes education is measured based on differences in quality of diabetes care in people with severe mental illness and diabetes treated at psychiatric outpatient clinics where all psychiatric nurses have participated in the diabetes education compared to psychiatric outpatient clinics where the psychiatric nurses have not participated in the diabetes education.

What are the possible benefits and risks of participating?

Benefits: For the psychiatric nurses to gain more knowledge and skills in diabetes treatment. For people with severe mental illness and diabetes, participating in the study, the benefit of participating is to gain better quality of diabetes care.

There is no risk of participating in the study as there is no extra blood test or other clinical test involved in this study. All the participants are asked to is to complete a baseline questionnaire and four follow-up questionnaires two years after the intervention. Moreover, the participants will give the research team access to data from the Danish Health care platform (medical journals) regarding their diabetes treatment and treatment of the psychiatric disease(s). The data will be stored in accordance with the GDPR regulations.

Where is the study run from?
Steno Diabetes Center Copenhagen, Denmark

When is the study starting and how long is it expected to run for?
April 2018 to March 2022

Who is funding the study?
1. The education department of Steno Diabetes Center Copenhagen
2. Jascha Foundation

Who is the main contact?
Lenette Knudsen
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

The effectiveness of Diabetes Education tailored to nurses in PSYchiatry (DEPSY): a pragmatic non-randomised controlled cluster study

Acronym

DEPSY

Study objectives

The overall hypothesis is that the intervention, the diabetes education, will improve indicators of quality of diabetes care measured on individuals with diabetes and severe mental illness in the intervention cluster during 12- and 24-months follow-up after the intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was submitted to ethical approval (Region Hovedstaden, Center for Sundhed, De Videnskabsetiske Komiteer, Kongens Vaenge 2, 3400 Hillerod, Denmark; +45 38 66 63 95; vek@regionh.dk) but Ethical Committee assessed the study as a quality development study and was therefore not assessed by the ethical committee

Study design

Single-center interventional pragmatic non-randomized controlled cluster study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Diabetes and severe mental illness

Interventions

The intervention is a 3-day diabetes education tailored to psychiatric nurses in psychiatric outpatient clinics. The diabetes education is provided to all nurses employed at four psychiatric outpatient clinics, approximately 70 nurses in total. The education aims to improve the quality of diabetes treatment for individuals with severe mental illness and diabetes. The overall aim of the education is to improve the nurses' diabetes knowledge and skills. The aim of the education is to provide the nurses with knowledge and skills which will give them the ability to identify and judge physical, mental and social changes for patients with severe mental illness and diabetes and support the patient in obtaining appropriate treatment of diabetes. The education is developed and conducted by the Department of Education at Steno Diabetes Center Copenhagen. The development of the intervention is based on a needs assessment lead by a team of both education and diabetes specialists (nurses, medical doctor, dietician and podiatrist) and health education researchers from the Department of Education to establish the nurses' current knowledge, skills and usual clinical practice. All nurses from the psychiatric outpatient clinics in the intervention group will participate in the intervention from February 2019 until December 2019.

The control group will receive standard of care, as provided by the Danish Health Care System which provides universal care to all.

The intervention group and control group were allocated in accordance with the regional organisation of psychiatric wards where it was possible to deliver the intervention.

Intervention Type

Behavioural

Primary outcome measure

1. Number of measurements and change in HbA1c levels collected two years prior to the intervention (baseline) and every 6 months 2 years after the intervention
2. Patient-reported outcomes measured in questionnaires collected one time before the intervention (baseline) and once every 6 months 2 years after the intervention. The patient-reported outcomes are based on the following scales SDSCA, PAID5, DAWN2 (tailored to people with both severe mental illness and diabetes), PACIC (tailored to people with both severe mental illness and diabetes), CARE (tailored to people with both severe mental illness and diabetes), WHO5 and SF36 and two new questions has been developed for the present study:
On a scale from 1 to 10 how much does diabetes impact your everyday life?
How relevant is it to receive diabetes-related support from your psychiatric nurse from the psychiatric outpatient clinic?

Secondary outcome measures

Measured two years before the intervention and every 6 months 2 years after the intervention:

1. Change in number of measured lipids, urine albumin /creatinine ratio, blood pressure, weight and BMI collected from electronic patient journals

2. Change in levels of lipids, urine albumin/creatinine ratio, blood pressure, weight and BMI collected from electronic patient journals
3. Change in number of prescriptions on diabetes-related medicine (glucose-, lipids and blood pressure lowering medicine) collected from electronic patient journals
4. Change in proportion of patients screened for diabetes complications collected based on questionnaires

Overall study start date

01/03/2018

Completion date

31/03/2022

Eligibility

Key inclusion criteria

1. Individuals diagnosed with diabetes and severe mental illness
2. Treated in one of the eight psychiatric outpatient clinics in the recruitment period
3. Aged ≥ 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Two groups: Intervention group: approx. 60 Individuals ≥ 18 years with type 1 or type 2 diabetes and severe mental illness treated in one of the four psychiatric outpatient clinics, where the psychiatric nurses have completed the diabetes education. Control group: approx. 60 Individuals ≥ 18 years with type 1 or type 2 diabetes and severe mental illness treated in one of the four psychiatric outpatient clinics, where the psychiatric nurses have not received diabetes education

Total final enrolment

107

Key exclusion criteria

1. Patients without diabetes
2. Patients not in the psychiatric outpatient clinics
3. Patients who do not wish to participate

Date of first enrolment

30/08/2018

Date of final enrolment

01/06/2019

Locations**Countries of recruitment**

Denmark

Study participating centre**Psychiatric Outpatient Center Ballerup**

Bygning 28A

Maglevænget 2

Ballerup

Denmark

2750

Study participating centre**Psychiatric Outpatient Center Gladsaxe**

Gladsaxe Møllevej 15, 1.sal

Søborg

Denmark

2860

Study participating centre**Psychiatric Outpatient Center Hillerød**

Dyrehavevej 48

Hillerød

Denmark

3400

Study participating centre**Psychiatric Outpatient Center Helsingør**

Esrumvej 143

Helsingør

Denmark

3000

Study participating centre**Psychiatric Outpatient Center Bispebjerg-Brønshøj**

Møntmestervej 17

København NV

Denmark
2400

Study participating centre

Psychiatric Outpatient Center Frederiksberg og Vanløse
Nimbusparken 24
Frederiksberg
Denmark
2000

Study participating centre

Psychiatric Outpatient Center Indre by og Østerbro
Strandboulevarden 96
København Ø
Denmark
2100

Study participating centre

Psychiatric Outpatient Center Nørrebro
Griffenfeldsgade 46
København N
Denmark
2200

Sponsor information

Organisation

Steno Diabetes Center

Sponsor details

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Gentofte
Denmark
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Sponsor type

Hospital/treatment centre

Website

<https://www.sdcc.dk/>

ROR

<https://ror.org/03w7awk87>

Organisation

Jascha Foundation

Sponsor details

Vedbæk stationsvej 18

Vedbæk

Denmark

2950

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info@jaschafonden.dk

Sponsor type

Charity

Website

<https://jaschafonden.dk/>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Steno Diabetes Center Copenhagen - Education Department

Funder Name

Jascha Foundation

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/01/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to national and regional data protection guidelines it is not possible to share the data even though the data is pseudonymised

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	528		17/11/2023	Yes	No
Other publications	652		17/11/2023	Yes	No
Other publications	Observational cross-sectional study	25/01/2022	17/11/2023	Yes	No
Results article		18/11/2024	19/11/2024	Yes	No